ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL-]

RIN - 2060-AM56

Protection of Stratospheric Ozone: Extension of Global Laboratory and Analytical Use Exemption for Essential Class I Ozone Depleting Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to extend the global laboratory and analytical use exemption for production and import of class I ozone-depleting substances from December 31, 2005, to December 31, 2007, consistent with recent actions by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer. The exemption allows persons in the United States to produce and import controlled substances for laboratory and analytical uses that have not been already identified by EPA as nonessential.

EFFECTIVE DATE: This final rule is effective on **[insert date of January 1, 2006]**.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OAR-2004-0064. All documents in the docket are listed in the EDOCKET index at http://www.epa.gov/edocket. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available either electronically in EDOCKET or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Hodayah Finman, U.S. Environmental Protection Agency, Office of Air and Radiation, Stratospheric Protection Division (6205J), 1200 Pennsylvania Avenue, N.W., Washington, D.C., 20460; telephone number: (202) 343-9246; fax numbers: (202) 343-2338; finman.hodayah@epa.gov. You may also visit the EPA's Ozone Depletion web site at www.epa.gov/ozone for further information about EPA's Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and other related topics.

SUPPLEMENTARY INFORMATION:

This final rule concerns the exemption for laboratory and analytical uses from CAA restrictions on the consumption and production of class I controlled substances. In May 2005, EPA proposed extending this exemption program from December 31, 2005, to December 31, 2007, consistent with action taken by the Parties to the Montreal Protocol (70 FR 25726, May 13, 2005). Today's action finalizes the proposed extension. In addition, the Agency solicited comment on clarifying the status of methyl bromide, a class I controlled substance, under the laboratory and analytical use exemption program. EPA is deferring final action on that aspect of the proposed rule.

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C., Chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the Federal Register. Today's final rule is issued under section 307(d) of the CAA, which states: "The provisions of section 553 through 557 . . . of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies." CAA section 307(d)(1). Thus, section 553(d) of the APA does not apply to this rule. EPA nevertheless is acting consistently with the policies underlying APA section 553(d) in making this rule effective on **[date of January 1, 2006]** APA section 553(d) provides an exception for any action that grants or recognizes an exemption or relieves a restriction. Today's final rule extends an exemption from the phaseout of class I ozone-depleting substances. Because the current exemption expires at the end of 2005, EPA is making this rule effective immediately to ensure that the exemption will not lapse.

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I. Background on The Montreal Protocol and the Global Laboratory and Analytical Use Exemption

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate the production and consumption[1] of all stratospheric ozone-depleting substances (ODSs). The elimination of production and consumption of ODSs is accomplished through adherence to phaseout schedules for specific class I ODSs[2], including: chlorofluorocarbons (CFCs), halons, carbon tetrachloride, and methyl chloroform. The Clean Air Act, as amended in 1990 and 1998, requires EPA to promulgate regulations implementing the Protocol's phaseout schedules in the United States. Those regulations are codified at 40 CFR Part 82. As of

[1] "Consumption" is defined as the amount of a substance produced in the United States, plus the amount imported into the United States, minus the amount exported to Parties to the Montreal Protocol (see Section 601(6) of the Clean Air Act). Stockpiles of class I ODSs produced or imported prior to the 1996 phase out may be used for purposes not expressly banned at 40 CFR part 82.

[2] Class I ozone depleting substances are listed at 40 CFR Part 82 subpart A, appendix A.

January 1, 1996, production and import of most class I ODSs were phased out in developed countries, including the United States.

However, the Protocol provides exemptions that allow for the continued import and/or production of ODSs for specific uses. Under the Protocol, for most class I ODSs, the Parties may collectively grant exemptions to the ban on production and import of ODSs for uses that they determine to be "essential." For example, with respect to CFCs, Article 2A(4) provides that the phaseout will apply "save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential." Similar language appears in the control provisions for halons (Art. 2B), carbon tetrachloride (Art. 2D), methyl chloroform (Art. 2E), hydrobromochlorofluorocarbons (Art. 2G), and bromochloromethane (Art. 2I). As defined by Decision IV/25 of the Parties, use of a controlled substance is essential only if (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

Decision X/19 under the Protocol (taken in 1998) allowed a general exemption for essential laboratory and analytical uses through December 31, 2005. EPA included this exemption in our regulations at 40 CFR part 82, subpart A. While the Clean Air Act does not specifically provide for this exemption, EPA determined that an exemption for essential laboratory and analytical uses was allowable under the Act as a de minimis exemption. EPA addressed the de minimis exemption in the final rule of March 13, 2001 (66 FR 14760-14770).

Decision X/19 also asked the Protocol's Technology and Economic Assessment Panel (TEAP), a group of technical experts from member countries, to report annually on procedures that could be performed without the use of controlled substances and stated that at future meetings the Parties would decide whether such procedures should no longer be eligible for exemptions. Based on the TEAP's recommendation, the Parties to the Protocol decided in 1999 (Decision XI/15) that the general exemption no longer applied to the following uses: testing of oil and grease, and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated this exclusion at Appendix G to Subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352).

Subsequently, in its May 2003 progress report the TEAP noted, "No new non-ODS methods have been forthcoming which would enable the TEAP to recommend the elimination of further uses of controlled substances for analytical and laboratory uses" (p. 106, see Air Docket OAR-2004-0064). Based on this statement, and in consideration of the pending cessation of the laboratory use exemption in 2005, the European Community proposed an extension of the exemption that would allow further time for development of non-ODS methods. At their fifteenth Meeting in November 2003, the Parties adopted the proposal in Decision XV/8, which extended the global exemption for laboratory and analytical uses to December 31, 2007.

EPA's regulations regarding this exemption at 40 CFR 82.8(b) currently state, "A global exemption for class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2005 subject to the restrictions in appendix G of this subpart, and subject to the record-keeping and reporting requirements at

§82.13(u) though (x). There is no amount specified for this exemption." Because certain laboratory procedures continue to require the use of class I substances in the United States, and because non-ODS replacements for the class I substances have not been identified for all uses, EPA is revising 40 CFR 82.8(b) to reflect the extension of the exemption to 2007 consistent with Decision XV/8. For a more detailed discussion of the reasons for the exemption, refer to the March 13, 2001, Federal Register notice.

II. Extension of the Global Laboratory and Analytical Use Exemption

With today's action, EPA is extending the laboratory and analytical use exemption from December 31, 2005, to December 31, 2007. This exemption allows for production and import of certain ODSs to meet laboratory and analytical needs.

EPA received three sets of comments on the proposed rule (70 FR 25726), two of which did not support extending the exemption and one late comment which did support extending the exemption. One commenter indicated that as long as there is an exemption program, industry will not have an incentive to seek alternatives. EPA believes that the time-limited nature of the exemption program, first through 2005 and now through 2007, does provide industry with an incentive to continue to explore alternatives. The Agency notes that many of the exempted uses are for niche applications or for experimental work of importance to society. For example, some federal and state laws, including regulations issued under the Clean Air Act and the Clean Water Act, require testing of the water, soil, or air to measure compliance with environmental standards. A pure sample of an ODS may be necessary to properly calibrate the testing equipment and effectively monitor the presence of chemicals of interest in the environment. A fuller description of laboratory

and analytical uses may be found in EPA's 2001 rulemaking on the topic (66 FR 14760) and in the comments in the accompanying paper docket #A-93-39.

Furthermore, EPA notes that total consumption (defined as production plus imports minus exports) for laboratory uses is small relative to baseline and has declined over time. The amount of phased-out class I substances being supplied to laboratories under this exemption decreased each year since 1997 to reach the level of eight metric tons in 2001 (approximately one-quarter the amount supplied in 1997), according to EPA's tracking system for ODSs.

Another commenter expressed concern that the exemption would be phased out "eventually" as described in the proposal and suggested that the exemption should last only another two years. In today's action, EPA is extending the laboratory and analytical use exemption by two years recognizing, however, that after December 2007 there still may be a need for this exemption. Should the Parties to the Montreal Protocol take a decision to further extend the exemption beyond 2007, EPA will seek comment on a new timeframe for the exemption.

The commenter continues to express concern that the exemption benefits companies at the expense of children and other members of the public. As described above, this exemption services the research and analytical community who are often engaged in work to protect the public. The laboratory and analytical exemption was agreed to by the Parties to the Montreal Protocol in Decisions X/19 and XV/8 as part of the careful balancing intrinsic in any public policy discussion. As discussed in the March 2001 notice, the controls in place for laboratory and analytical uses provide adequate assurance that very little, if any, environmental damage will result from the handling and disposal

of the small amounts of class I ODSs used in such applications. Therefore, EPA does not anticipate significant environmental impacts on the ozone layer as a result of today's action.

III. Applicability of the Global Laboratory and Analytical Use Exemption to Methyl Bromide

As of January 1, 2005, production and import of methyl bromide is no longer allowed in the United States, except for limited exemptions (40 CFR 82.4(d)). Methyl bromide is a class I controlled substance used chiefly as a fumigant for soil treatment and pest control. In the proposed rule, EPA sought comment on whether the global laboratory exemption should include methyl bromide and also sought information on laboratory and analytical processes that involve the use of small quantities of methyl bromide. EPA only received one comment and it was general in nature. The commenter indicated that she did not support any exemptions for methyl bromide. Recognizing that further discussion of whether the global laboratory exemption should include methyl bromide may occur at a future meeting of the Parties to the Montreal Protocol, EPA is deferring final action on this aspect of the proposed rule.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 [58 Federal Register 51735 (October 4, 1993)], the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines

"significant regulatory action" as one that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose any new information collection burden because EPA is not creating new information or reporting requirements. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations, as part of the final rule promulgated by the Agency on May 10, 1995, under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2060-0170 (EPA ICR number 1432.21). A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by calling (202) 566-1672.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule.

For purposes of assessing the impact of today’s rule on small entities, the term small entities is defined as: (1) a Pharmaceutical preparations manufacturing business (NAICS code 325412); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today’s final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a

substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the proposed rule on small entities." 5 U.S.C. Sections 603 and 604. Thus, an agency may conclude that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule."

This rule provides an otherwise unavailable benefit to those companies that obtain ozone depleting substances under the essential laboratory and analytical use exemption. We have therefore concluded that today's final rule will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt

the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector, since it merely extends the availability of an already available exemption to the ban on production and import of class I ODSs. For the same reason, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order No. 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism

implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's rule affects only the companies that produce or import class I ozone-depleting substances for laboratory or analytical uses. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order No. 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order No. 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This final rule does not have tribal implications, as specified in Executive Order No. 13175. Today's final rule does not significantly or uniquely affect the communities of Indian tribal governments. The final rule does not impose any enforceable duties on communities of Indian tribal governments. Thus, Executive Order No. 13175 does not apply to this final rule.

G. Executive Order No. 13045: Protection of Children from Environmental Health & Safety Risks

Executive Order No. 13045: “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Depletion of stratospheric ozone results in greater transmission of the sun’s ultraviolet (UV) radiation to the earth’s surface. The following studies describe the effects on children of excessive exposure to UV radiation: (1) Westerdahl J, Olsson H, Ingvar C. ‘‘At what age do sunburn episodes play a crucial role for the development of malignant melanoma,’’ Eur J Cancer 1994; 30A: 1647–54; (2) Elwood JM, Jopson J. ‘‘Melanoma and sun exposure: an overview of published studies,’’ Int J Cancer 1997; 73:198–203; (3) Armstrong BK. ‘‘Melanoma: childhood or lifelong sun exposure’’ In: Grobb JJ, Stern RS, Mackie RM, Weinstock WA, eds. ‘‘Epidemiology, causes and prevention of skin diseases,’’ 1st ed. London, England: Blackwell Science, 1997: 63–6; (4) Whiteman D., Green A. ‘‘Melanoma and Sunburn,’’ Cancer Causes Control, 1994: 5:564–72; (5) Kricker A, Armstrong, BK, English, DR, Heenan, PJ. ‘‘Does intermittent sun exposure cause basal cell carcinoma? A case control

study in Western Australia,'' Int J Cancer 1995; 60: 489–94; (6) Gallagher, RP, Hill, GB, Bajdik, CD, et. al. ''Sunlight exposure, pigmentary factors, and risk of nonmelanocytic skin cancer I, Basal cell carcinoma,'' Arch Dermatol 1995; 131: 157–63; (7) Armstrong, BK. ''How sun exposure causes skin cancer: an epidemiological perspective,'' Prevention of Skin Cancer. 2004. 89– 116. The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life sun exposure.

However, as discussed in the March 13, 2001, Federal Register notice, the laboratory and analytical applications addressed in today's proposed rule involve extremely controlled use and disposal of all chemicals, including any ODS. As a result, emissions of ODS into the atmosphere are negligible. In light of the conditions already applied to the global exemption by appendix G to subpart A of 40 CFR part 82, EPA believes that any additional controls on laboratory uses would provide little, if any, benefit.

H. Executive Order No. 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order No. 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law. No. 104-113, Section 12(d) (15

U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A Major rule cannot take effect until 60 days after it is published in the Federal Register. This action is not a "major rule" as defined by 5 U.S.C. §804(2). This rule will be effective on **[insert date of January 1, 2006]**.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedures, Air pollution control, Chemicals, Exports, Imports, Ozone, Production, Reporting and recordkeeping requirements, and Treaties.

Dated: _____

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Stephen L. Johnson, Administrator

40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671-7671q.

Subpart A—Production and Consumption Controls

2. Section 82.8 is amended by revising paragraph (b) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

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(b) A global exemption for class I controlled substances for essential laboratory and analytical uses shall be in effect through December 31, 2007, subject to the restrictions in appendix G of this subpart, and subject to the record keeping and reporting requirements at Sec. 82.13(u) through (x). There is no amount specified for this exemption.

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